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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/851,873	05/08/2001	Rolf F. Kletzien	28341/00233.NCP	4967

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EXAMINER

HUTSON, RICHARD G

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 09/25/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/851,873

Applicant(s)

KLETZIEN ET AL.

Examiner

Richard G Hutson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-49 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-8, drawn to an isolated caspase polypeptide, classified in class 435, subclass 219.
- II. Claim 9-30, drawn polynucleotide that encodes a caspase polypeptide, vectors and host cells comprising said polypeptide and methods of expressing said polynucleotide, classified in class 435, subclass 219.
- III. Claims 31-33, drawn to an antibody and hybridoma for producing said antibody, classified in class 530, subclass 387.1.
- IV. Claims 34-37, drawn to methods of identifying candidate inhibitors or activators of human caspase-12, classified in class 435, subclass 69.1.
- V. Claim 38 and 39, drawn to a method of identifying a candidate inhibitors of binding of human caspase-12 to a binding partner, classified in class 435, subclass 69.1.
- VI. Claims 40-44, 47 and 48, drawn to a method of treating a disorder involving inappropriate apoptosis comprising administering an inhibitor of caspase-12, classified in class 514, subclass 789.
- VII. Claims 45 and 46, drawn to a method of treating a disorder involving excessive proliferation comprising administering caspase-12, classified in class 424, subclass 94.65.

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VIII. Claim 49 drawn to a method of delivering a human caspase-12 polynucleotide to a subject using a vector comprising said polynucleotide, classified in class 514, subclass 44.

For each of inventions I-VII above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of inventions I-VII and one of inventions (A)-(A').

- (A). SEQ ID NO: 1 or a sequence encoding SEQ ID NO: 2.
- (B). SEQ ID NO: 3 or a sequence encoding SEQ ID NO: 4.
- (C). SEQ ID NO: 5 or a sequence encoding SEQ ID NO: 6.
- (D). SEQ ID NO: 7 or a sequence encoding SEQ ID NO: 8.
- (E). SEQ ID NO: 50 or a sequence encoding SEQ ID NO: 51.
- (F). SEQ ID NO: 52 or a sequence encoding SEQ ID NO: 53.
- (G). SEQ ID NO: 54 or a sequence encoding SEQ ID NO: 55.
- (H). SEQ ID NO: 56 or a sequence encoding SEQ ID NO: 57.
- (I). SEQ ID NO: 58 or a sequence encoding SEQ ID NO: 59.
- (J). SEQ ID NO: 60 or a sequence encoding SEQ ID NO: 61.
- (K). SEQ ID NO: 62 or a sequence encoding SEQ ID NO: 63.
- (L). SEQ ID NO: 64 or a sequence encoding SEQ ID NO: 65.
- (M). SEQ ID NO: 66 or a sequence encoding SEQ ID NO: 67.
- (N). SEQ ID NO: 68 or a sequence encoding SEQ ID NO: 69.
- (O). SEQ ID NO: 70 or a sequence encoding SEQ ID NO: 71.
- (P). SEQ ID NO: 72 or a sequence encoding SEQ ID NO: 73.

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- (Q). SEQ ID NO: 74 or a sequence encoding SEQ ID NO: 75.
- (R). SEQ ID NO: 76 or a sequence encoding SEQ ID NO: 77.
- (S). SEQ ID NO: 78 or a sequence encoding SEQ ID NO: 79.
- (T). SEQ ID NO: 9.
- (U). SEQ ID NO: 10.
- (V). SEQ ID NO: 39.
- (W). SEQ ID NO: 41.
- (X). SEQ ID NO: 42.
- (Y). SEQ ID NO: 43.
- (Z). SEQ ID NO: 48.
- (A'). SEQ ID NO: 49.

The inventions are distinct, each from the other because of the following reasons:

Inventions (A)-(A') are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, represent structurally different polypeptides and the polynucleotides encoding them. Therefore, where structural identity is required, such as for hybridization or expression, the different sequences have different effects.

Inventions I, II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

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operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the caspase polypeptide of Group I, the nucleic acid encoding the caspase polypeptide of Group II and the antibody against the caspase polypeptide of Group III each comprise a chemically unrelated structure capable of separate manufacture, use and effect. The peptides of Groups I and III are comprised of different amino acid sequences and the DNA of Group II is comprised of nucleic acid sequence. The DNA has other utility besides encoding protein such as a hybridization probe, and the proteins can be made synthetically. Additionally, the protein can be used to perform specific biological function(s) which are independent of the function(s) of the DNA molecule. The protein has other utility such as for methods of production of antibodies against the protein.

Inventions I and IV, V and VII are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptide of Group I can be used in a materially different process such as one in which the polypeptide is used to synthesize antibodies against the polypeptide.

The polynucleotide of Group II, the antibody of Group III, are unrelated to the methods of Groups IV-VII as they are neither used nor made by the method of Groups IV-VII.

The polypeptide of Group I is unrelated to the methods of Groups VI as they are neither used nor made by the method of Group VI.

Inventions II and VIII are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polynucleotide of Group II can be used in a materially different process such as one in which the polynucleotide is used to detect similar polynucleotides through hybridization assays.

The polypeptide of Group I and the antibody of Group III are unrelated to the method of Group VIII as they are neither used nor made by the method of Group VIII.

The methods of Groups V-VIII are independent as they comprise different steps, utilize different products and produce different results.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the literature and sequence searches required for each of the Groups are not required for another of the Groups, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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A handwritten signature in black ink, appearing to read 'Richard Hutson', with a long horizontal line extending to the right.

Richard Hutson, Ph.D.

Patent Examiner

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September 20, 2002